

### **Remarks**

This Amendment is in response to the Office Action dated **December 31, 2007**. Claims 9, 10 and 13-30 are pending in this application. The Office Action rejected claims 17, 20, 29 and 30 under 35 USC § 102 over Pinchasik (US 5449373); rejected claims 17, 20, 29 and 30 under 35 USC § 102 over Palmaz (US 5102417) in view of Kleshinski (US 5902317); rejected claims 9, 10, 13, 16 and 21-28 under 35 USC § 103 over Pinchasik in view of Kleshinski; rejected claims 9, 10, 13, 16 and 21-28 under 35 USC § 103 over Palmaz in view of Kleshinski; rejected claims 14, 15, 18 and 19 under 35 USC § 103 over Palmaz or Pinchasik in view of Kleshinski and further in view of Lau (US 5514154); rejected claims 22 and 29 under 35 USC § 112, first paragraph; and objected to claim 17 due to an informality.

By this Amendment, claims 9, 16 and 17 are amended and claims 23 and 27 are cancelled without prejudice or disclaimer. Specifically, the limitations from claims 23 and 27 have been incorporated into independent claims 9 and 16, respectively, and claim 17 is amended for clarification purposes only. Applicants reserve the right to prosecute all cancelled subject matter in a subsequent patent application claiming priority to the immediate application. Reconsideration in view of the above amendments and the following remarks is requested.

### **Claim Objections**

The Office Action objects to claim 17, alleging that the claim lacks an antecedent for “the peaks of the proximal portion,” and for “the valleys” recited with respect to the distal portion.

Claim 17 is amended for clarification purposes, and now positively recites “the proximal portion including a plurality of said peaks, the distal portion including a plurality of said valleys.” Therefore, antecedent basis is provided for the recitation of “the peaks of the proximal portion being offset circumferentially from the valleys of the distal portion relative to the circumference of the body.”

Applicants request withdrawal of the objection to claim 17.

### **Claim Rejections - 35 USC § 112**

The Office Action rejected claims 22 and 29 under 35 USC § 112, first paragraph.

Claims 22 and 29 recite connecting members that are “non-parallel to a stent longitudinal axis.” The Office Action alleges that the full scope of claims 22 and 29 are not enabled. See Office Action at page 2. These rejections are traversed.

Applicants assert that the rejection has not presented a *prima facie* case of non-enablement against claims 22 and 29.

The enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation. See *AK Steel Corp. v. Sollac*, 68 USPQ2D 1280 (Fed. Cir. 2003). It is not necessary that the specification describe how to make and use every possible variant of the claimed invention, for the artisan’s knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art. See *AK Steel Corp. v. Sollac*, 68 USPQ2D 1280 (Fed. Cir. 2003). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). According to *In re Bowen*, 492 F.2d 859, 862-63, 181 USPQ 48, 51 (CCPA 1974), the minimal requirement is for the examiner to give reasons for the uncertainty of the enablement. This standard is applicable even when there is no evidence in the record of operability without undue experimentation beyond the disclosed embodiments. See also MPEP § 2164.04.

The rejection admits that “angularly” or “diagonally” extending connecting members are enabled, but alleges that “curved” or “perpendicular” connecting members are not enabled. The rejection amounts to a conclusory statement that connectors that do not extend “angularly” or “diagonally” are non-enabled. The rejection does not discuss any reasons why a person of ordinary skill in the art must perform undue experimentation in order to practice a stent wherein the connectors would be “curved” or “perpendicular.” For example, MPEP § 2164.01(a) lists factors that should be considered when evaluating whether any necessary experimentation is “undue.” The rejection does not discuss any of these factors.

Therefore, Applicants assert that the Office Action has not presented a *prima facie* case of non-enablement against claims 22 or 29. Accordingly, Applicants request withdrawal of the rejections under 35 USC § 112, first paragraph.

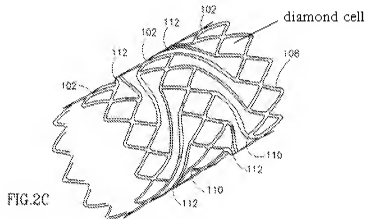
#### **Claim Rejections – 35 USC § 102 (Pinchasik)**

The Office Action rejected claims 17, 20, 29 and 30 under 35 USC § 102 over Pinchasik. These rejections are traversed.

Claim 17 previously recited a “stent having a plurality of cells, each cell defined by two connecting members and portions of two different serpentine bands” (emphasis added). Applicants presented an argument regarding the “each cell” limitation in the Amendment filed October 29, 2007. The Office Action does not comment on the argument.

Applicants have amended claim 17 for clarification purposes only, to specify that “each cell of the stent” is “defined by two connecting members and portions of two different serpentine bands.” Thus, claim 17 requires each cell of the stent to be at least partially defined by “connecting members.”

The rejection characterizes Pinchasik segments 102 as the claimed “serpentine bands” and the Pinchasik links 112 as the claimed “connecting members.” See Office Action at page 5.



Pinchasik does not meet the language of claim 17 because some of the “cells” are not bounded by a link 112. See e.g. annotated Figure 2C of Pinchasik, provided above. Each segment 102 includes cells that are defined entirely by the segment/“band” structure. For

example, see the cell marked “diamond cell” in Figure 2C above.

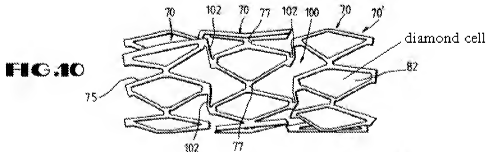
Therefore, Applicants assert that Pinchasik does not disclose or suggest each limitation of claim 17, and that claim 17 is patentable over Pinchasik under 35 USC § 102. Claims 20, 29 and 30 each depend from claim 17 and are patentable over Pinchasik for at least the reasons discussed with respect to claim 17. Accordingly, Applicants request withdrawal of the rejections under 35 USC § 102 over Pinchasik.

#### Claim Rejections – 35 USC § 102

The Office Action rejected rejected claims 17, 20, 29 and 30 under 35 USC § 102 over Palmaz in view of Kleshinski. Applicants note that although the rejection combines Palmaz with Kleshinski, the rejection does not discuss Kleshinski. Therefore, Applicants have assumed the citation of Kleshinski was in error, and have treated the rejection under 35 USC § 102 as a rejection over Palmaz alone.

Claim 17 previously recited a “stent having a plurality of cells, each cell defined by two connecting members and portions of two different serpentine bands” (emphasis added). Applicants presented an argument regarding the “each cell” limitation in the Amendment filed October 29, 2007. The Office Action does not comment on the argument.

Applicants have amended claim 17 for clarification purposes only, to specify that “each cell of the stent” is “defined by two connecting members and portions of two different serpentine bands.” Thus, claim 17 requires each cell of the stent to be at least partially defined by “connecting members.”



Palmaz does not meet the language of claim 17 because some of the “cells” are not bounded by a connector member 102. See e.g. annotated Figure 10 of Palmaz, provided above.

Each expandable member 70 includes cells that are defined entirely by the expandable member/"band" structure. For example, see the cell marked "diamond cell" in Figure 10 above.

Therefore, Applicants assert that Palmaz does not disclose or suggest each limitation of claim 17, and that claim 17 is patentable over Palmaz under 35 USC § 102. Claims 20, 29 and 30 each depend from claim 17 and are patentable over Palmaz for at least the reasons discussed with respect to claim 17. Accordingly, Applicants request withdrawal of the rejections under 35 USC § 102 over Palmaz (in view of Kleshinski).

### **Claim Rejections – 35 USC § 103**

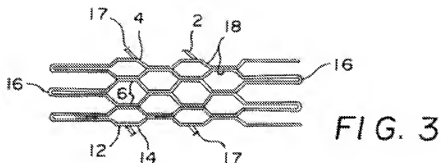
The Office Action rejected, under 35 USC § 103, claims 9, 10, 13, 16 and 21-28 over Pinchasik in view of Kleshinski; claims 9, 10, 13, 16 and 21-28 over Palmaz in view of Kleshinski; and claims 14, 15, 18 and 19 over Palmaz or Pinchasik in view of Kleshinski and further in view of Lau. The rejections with respect to claims 18, 19, 23 and 27 are traversed.

Independent claims 9 and 16 have been amended to incorporate the limitations of claims 23 and 27, respectively. Therefore, independent claims 9 and 16 each recite, "wherein each cell of the stent is bounded at a first end by a portion of one annular element, at a second end by a portion of another annular element, and by two connecting members which extend between the one annular element and the other annular element."

Independent claim 17, from which claims 18 and 19 depend, recites, "each cell of the stent defined by two connecting members and portions of two different serpentine bands."

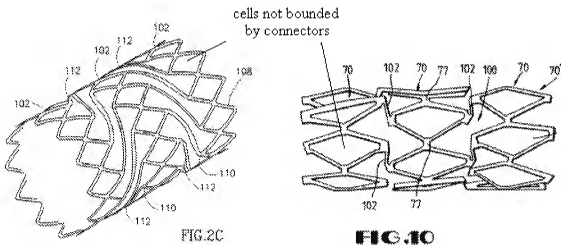
Applicants assert that even if the modifications to the prior art proposed in the rejections were performed, the resulting devices would not meet the limitations of any of independent claims 9, 16 or 17.

Kleshinski teaches a self-expanding stent having a tubular body portion 14 and fingers 16 at the ends. See Figure 3, provided below. The fingers 16 "facilitate a gradual reduction in radially outward extending pressure exerted by the stent." See column 4, lines 5-8.



The Office Action proposes to add Kleshinski's fingers 16 to the ends of the stents disclosed by Pinchasik or Palmaz. See Office Action at pages 5-6.

Pinchasik and Palmaz each teach stents that do not meet the limitations of the independent claims. Each discloses expandable segments that define cells that are bounded entirely by the structure of the expandable segment, and not by any connector. See annotated Figure 2C of Pinchasik and annotated Figure 10 of Palmaz, provided below, each marked to indicate a cell bounded entirely by the expandable segment structure.



Even if the Kleshinski fingers 16 were added to either of the stents shown above, the resulting device would include the cells that are not bounded by a “connecting member.” Therefore, the resulting device would not meet the limitations of any of the pending claims, and the combination of Pinchasik or Palmaz in view of Kleshinski does not render the pending claims unpatentable under 35 USC § 103.

Lau was applied for the disclosure of Nitinol, and the rejection proposes to make

the stent of Pinchasik or Palmaz as modified by Kleshinski from Nitinol. See Office Action at page 6. Even if such a modification were performed, the resulting device would not meet the limitations of the pending claims. The modification in view of Lau would not change the cells that are not bounded by connectors. Therefore, Applicants assert that the addition of Lau does not render the pending claims unpatentable under 35 USC § 103.

Accordingly, Applicants request withdrawal of all rejections under 35 USC § 103.

### **Conclusion**

Based on at least the foregoing amendments and remarks, Applicants respectfully submit this application is in condition for allowance. Favorable consideration and prompt allowance of claims 9, 10, 13-22, 24-26 and 28-30 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: April 7, 2008

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